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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Finnegan Henderson Farabow
Garrett & Dunner
1300 I Street NW
Washington, DC 20005

EXAMINER

GRASER, JENNIFER E

ART UNIT


PAPER NUMBER

1645

DATE MAILED: 01/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/555,139	Applicant(s) Agsteribbe et al.	
Examiner Jennifer Graser	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 20) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear what is encompassed by the term "particulate immunogen". The Webster's II New Riverside University Dictionary defines the word 'particulate' as "Of, relating to, or made up of separate particles". Clarification is requested. Based on the dictionary definition, a "protein or peptide" is being considered to encompass the scope of the term a 'particulate immunogen' for the purposes of this examination.

In claim 3, "claim 1-2" should be changed to "claim 1 or 2".

Claims 1-9 are vague and indefinite for the term "adjuvanting amount". How is this amount quantitated?

Claim 4 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n).

Claims 8 and 9 are vague and indefinite because it is unclear what is meant by a "common mucosal immune response". Appropriate correction is requested.

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Claims 8 and 9 provide for the use of the B subunits, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 8 and 9 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamura et al. (US 5,182,109).

Tamura et al disclose a vaccine preparation comprising in combination a vaccine and a bacterial toxin adjuvant. It is specifically disclosed that the toxin can be a B subunit of *E.coli* heat-labile enterotoxin or part of said B subunit, i.e., completely free of A subunit or toxic LT holotoxin. It is further taught that the vaccine contained in the vaccine preparation can be

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influenza vaccine. Tamura teach that the vaccine can be intranasal vaccine or can be in injectable form, spray form or oral administration form. Methods for the induction of a mucosal immune response as well as a systemic immunoglobulin response are also taught.

5. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirst et al (WO 90/06366).

Hirst et al disclose heat-labile toxin B subunit fusion proteins. The fusion proteins are prepared by recombinant DNA methodology. The LTB gene was well known. Page 5, lines 10-17, disclose a means for recombinantly producing the LTB subunit. It is disclosed that fusion proteins in which an antigen or epitope is fused to the carboxy-end of LTB represents a way of effectively presenting the antigen or epitope to the immune system. LTB is the carrier for the antigen/epitope. It is disclosed that any amino acid sequence having biological activity may be fused to the carboxy-terminus of the LTB. The antigen or epitope may be derived from a virus, bacterium, fungus, yeast or parasite. More specifically, the antigen may be derived from influenza virus, see page 3, line 23. It is also taught that attenuated live vaccines capable of expressing the fusion protein or killed toxigenic strains of E.coli in which the fusion protein has been expressed may also be used as vaccines. The vaccine may be administered orally, parenterally, or by any convenient means.

Claim Rejections - 35 USC § 103

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tamura et al (US 5,182,109) as applied to claims 1 and 3-9 above, and further in view of Hirst et al (WO 90/06366).

The teachings of Tamura et al are set forth above. However, they do not specifically teach that the LTB may be prepared recombinantly.

Hirst et al teach that the LTB gene was well known. Page 5, lines 10-17, disclose a means for recombinantly producing the LTB subunit. Additionally, official notice is taken that the recombinant production of a protein whose nucleotide sequence was well known in the prior art was routine. Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare the LTB used in the Tamura compositions recombinantly because doing so would allow for large amounts of LTB to be prepared in a more efficient and time consuming manner. The recombinant LTB would be a functional equivalent to the LTB used by Hirst.


8. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jennifer Graser
Primary Examiner
Art Unit 1645